JUN 2 7 2002

K021797

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 – Facsimile
Colleen Boswell – Contact Person

Date Summary Prepared: May 2002

Device Name:

- Trade Name – *L.E.Demetron*
- Common Name – Cordless LED Curing Light
- Classification Name – Ultraviolet activator for polymerization, per 21 CFR § 872.6070

Devices for Which Substantial Equivalence is Claimed:

- 3M ESPE AG, *Elipar FreeLight*

Device Description:

The *L.E.Demetron* Cordless Curing Light is a device used for the polymerization of dental materials using visible light. It consists of a cordless LED curing handpiece, a battery pack, a battery charger with built-in radiometer, and a remote handpiece holder. The plastic molded handpiece will contain a detachable rechargeable battery pack, an LED light "engine", and a cooling fan. A printed circuit board with a digital circuit will be utilized to control three (3) different curing modes. Each mode specifies LED timing, fan timing and audible beep timing. A segmented display will depict the curing mode and LED timing. A pushbutton switch will be used to scroll between the curing modes. A separate pushbutton "trigger switch" will activate the light. The molded plastic battery charger will have a single well for charging the battery pack, and indictor lights to indicate battery charge status. Indictor lights will also depict light output from the built-in radiometer.

Intended Use of the Device:

The intended use of the *L.E.Demetron* is for the polymerization of visible light cured materials.

Substantial Equivalence:
L.E.Demetron is substantially equivalent to other legally marketed devices in the United States. *L.E.Demetron* functions in a manner similar to and is intended for the same use as the *Elipar FreeLight* designed by 3M ESPE AG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2002

Ms. Colleen Boswell
Director, Corporation Compliance
Sybron Dental Specialties, Inc.
1717 West Collins Avenue
Orange, California 92867

Re: K021797
Trade/Device Name: L.E.Demetron
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: May 28, 2002
Received: May 31, 2002

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Kerr Corporation

510(k) Number (if known): K021797

Device Name: L.E.Demetron

Indications For Use:

The *L.E.Demetron* is a cordless LED curing light intended for polymerization of visible light cured materials.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021797

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)